

### REMARKS

Claims 1-3 and 5-52 are pending in the application, with claims 1-2, 15-47 and 49-52 having been withdrawn from consideration. Claim 4 has been cancelled and claim 3 has been amended to include the limitation therein. Claim 5 has been amended to depend from claim 3. Likewise, claim 9 has been amended to recite that the *P. falciparum* MSP-1<sub>42</sub> protein is obtained from strain 3D7, and to correct a typographical error (so that the first step of the method properly recites "protein" rather than "proteins"). No new matter has been added. Claims 3, 5-14 and 48 are under examination. Reconsideration is requested.

The disclosure was objected to for lack of complete information. Amendment to the specification has been made to include information about the biological deposit. No new matter has been added.

#### Rejection Under 35 U.S.C. § 112, first paragraph

Claims 3-14 and 48 were rejected under 35 U.S.C. §112, first paragraph, as failing to provide an enabling disclosure without complete evidence that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of biological materials. The specification has been amended to insert the deposit information. Applicants confirm that upon the granting of a patent, the deposit will be freely available to the public without restrictions and that the deposit will be maintained for the required period of not less than 30 years or 5 years beyond the date of the last request for a sample was made. Withdrawal of the rejection is accordingly requested.

#### Rejection Under 35 U.S.C. § 102

Claim 3 was rejected under 35 U.S.C. §102(b) as being anticipated by Kumar et al., 1995, Molecular Medicine 1, pages 325-332. It was the Examiner's position that Kumar et al. disclose a recombinant vector pGEX3 comprising a DNA sequence encoding MSP-1<sub>42</sub>. Claim 3 was also

rejected under 35 U.S.C. §102(b) as being anticipated by Chang et al., 1996, Infection and Immunity 64: pages 253-261. It is the Examiner's position that Chang et al. disclose a recombinant vector pGEX3 comprising a DNA sequence encoding MSP-1<sub>42</sub>. Although Applicants disagree, in order to advance prosecution, claim 3 has been amended to include the limitation that the DNA is from *Plasmodium falciparum* 3D7. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 9-10 were rejected under 35 U.S.C. §102(b) as being anticipated by Kumar et al., 1995. It is the Examiner's position that the claims are drawn to a method for producing and purifying recombinant *P. falciparum* MSP-1<sub>42</sub> protein comprising growing a host cell containing vector expressing said protein, lysing said host cells to recover said recombinant protein, and that Kumar et al. disclose a method of producing and purifying recombinant MSP-1<sub>42</sub> from *P. falciparum*, electroplating into *E. coli*, growing bacterial cells in the presence of IPTG to induce the high expression of recombinant protein and recovering recombinant MSP-1<sub>42</sub> to be used as a vaccine in Aotus monkeys.

Although Applicants continue to disagree with the Examiner's position, in order to advance prosecution, claim 9 has been amended to recite that the expressed protein is from *P. falciparum* 3D7. It is respectfully submitted that Kumar does not disclose any information about the recited strain or protein. Reconsideration and withdrawal of the rejection are respectfully requested.

#### Rejections under 35 U.S.C. § 103

Claims 9-14 and 48 were rejected under 35 U.S.C. §103 as being unpatentable over Kumar et al 1995, Molecular medicine 1, pages 325-332 in view of short Protocols in Molecular Biology (Ausubel). According to the Examiner's position, Kumar teaches a method of producing and purifying recombinant *P. falciparum* MSP-1<sub>42</sub> from vector pGEX2, and further, Ausubel teaches protein expression in various vectors including thioredoxin fusion proteins, growing the

expression vectors containing DNA encoding proteins that are induced by IPTG at various temperatures in the presence of fungicides, antibiotics and purifying proteins from *E. coli* containing pET vectors using Ni-NTA column to remove endotoxin, etc.

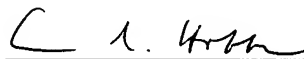
As noted above, claim 9 has been amended to recite applicant's preferred embodiment of MSP-1<sub>42</sub> protein from *P. falciparum* 3D7. This protein is not disclosed or suggested in either Kumar or Aubusel. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants appreciate the Examiner's indication that Claims 4-8 are free of the prior art. Claim 4 has been cancelled and claim 3 has been rewritten to include the limitations thereof. In view of the deposit of biological material, it is believed that claims 3, and 5-8 are in condition for allowance.

All objections and rejections having been addressed, it is respectfully submitted that the application is in condition for allowance, and Notice to that effect is respectfully requested. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Respectfully submitted,

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